

**TAB 51**



Boehringer Ingelheim  
Roxane Laboratories

*Roxane Labs, Inc.*  
*Year End 2004*  
*&*  
*Commentary*



Boehringer Ingelheim  
Roxane Laboratories

Actual 2004

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## 1. Management Summary

The 2% savings requested by Headquarters of \$5.7 Million for Budget 2004 are reflected on RLI Legal Entity, PNR 8742 or Income / Expense II. For Year End 2004 these savings are reflected throughout the organization, on different PNRs.

From a Legal Entity perspective, the decision to establish a TMA with BII for Spiriva and Tipranavir products was strategically important, in the sense that it created a direct relationship between RLI and BII without the intermediation of BIPI.

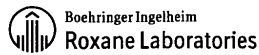
RLI's financial outcome for year of 2004 was influenced by the following major points:

- Multisource:
  - Delayed Fluticasone launch due to FDA approval issues, resulting in \$52.7 Million in lost sales and additional product write offs of \$21 Million.
  - Delayed Clonidine launch due to lack of generic competition, resulting in \$9.0 Million in lost sales.
  - A total of 13 new products were launched, which generated \$21.9 Million in Net Sales.
  - A record 18 ANDAs were submitted, 17 ANDAs were approved.
- Affiliates:
  - Higher production demand for Mobic and Viramune
  - Lower production demand for Spiriva, which caused higher cost of reserved capacity and production variances
  - Write-offs of Spiriva Robots



Actual 2004

<b>ROXANE LABS, INC.</b> <b>PRESCRIPTION MEDICINE BY PRODUCT</b> <b>Multisource Net Sales</b> <b>Year End 2004 vs. Budget 2004</b>				
Thousands U.S.\$				
	Actual 2003	Budget 2004	Year End 2004	Year End 2004 Over (Under) Budget 2004
<b>TOP 10 PRODUCTS</b>				
MEGESTROL AC	27,798	10,612	26,046	15,434
PREDNISONE	25,077	20,830	24,114	3,284
METHADONE	17,451	13,578	17,484	3,906
ROXICET	14,029	3,103	14,195	11,092
CLOTRIMAZOLE	-	11,665	9,747	(1,918)
AZATHIOPRINE	9,624	6,819	9,626	2,807
MERCAPTOPURINE	-	12,187	8,474	(3,713)
DEXAMETHASON	7,288	3,583	8,427	4,844
FLUTICASONE	-	52,680	-	(52,680)
CLONIDINE	-	9,042	-	(9,042)
Other Products	112,613	119,106	93,458	(25,648)
Discontinued Products	(194)	-	(201)	(201)
<b>Net Sales</b>	<b>213,686</b>	<b>263,205</b>	<b>211,370</b>	<b>(51,835)</b>
<b>NEW LAUNCHES IN 2004</b>				
FLUTICASONE		52,680	-	(52,680)
MERCAPTOPURINE		12,187	8,474	(3,713)
CLOTRIMAZOLE		11,665	9,747	(1,918)
CLONIDINE		9,042	-	(9,042)
FLUCONAZOLE		6,274	852	(5,422)
METOLAZONE		4,079	-	(4,079)
ANAGRELIDE		1,406	-	(1,406)
MEFLOQUININE		1,077	184	(893)
LITHIUM CR		834	2,638	1,804
<b>TOTAL</b>		<b>99,243</b>	<b>21,895</b>	<b>(77,348)</b>



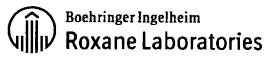
Actual 2004

## 2. Businesses (6A-MS, 6E-3P Mfg, 6G-Affiliates)

### 2.1. 6A – Multisource

#### PNR 8100: Net Sales

- Down \$51.8 Million
  - **Megestrol:** up \$15.4 Million due primarily to less price erosion than anticipated.
  - **Prednisone:** up \$3.2 Million.
  - **Methadone:** up \$3.9 Million due to improved pricing and unit sales.
  - **Roxicet:** up \$11.1 Million due to increased unit sales. Prices have fallen by half, but units have increased more than 4 times over budget.
  - **Clotrimazole:** down \$1.9 Million due to delayed launch.
  - **Azathioprine:** up \$2.8 Million due to less price erosion than anticipated.
  - **Mercaptopurine:** down \$3.7 Million due to budget overestimate of December sales.
  - **Dexamethason:** up \$4.8 Million due to increased sales units.
  - **Fluticasone:** down \$52.7 Million due product not being launched.
  - **Clonidine:** down \$9.0 Million due to no generic competition for Catapres TTS.
  - **Other Products with substantial variance:**
    - Fluconazole is down \$5.0 Million
    - Metolazone is down \$4.1 Million
    - Lithium CR is up \$1.8 Million



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**ROXANE LABORATORIES, INC.**  
**INCOME STATEMENT**  
**PRESCRIPTION MEDICINE**  
**Multisource**  
**Year End 2004 vs. Budget 2004**

Thousands U.S.\$

		Year End	Budget	Year End	Year End 2004	Variance
	PNR	2003	2004	2004	Over (Under) Budget 2004	%
Gross Sales of Goods	8030	323,790	788,197	388,568	(399,629)	-50.7%
Sales Discounts	8050	110,104	524,992	177,198	(347,794)	-66.2%
Product Net Sales		213,686	263,205	211,371	(51,834)	-19.7%
Royalty Income	8080	-	-	-	-	-
Other Income	8090	-	-	-	-	-
Net Sales	8100	213,686	263,205	211,370	(51,835)	-19.7%
Standard Cost of Goods Sold	8200	103,382	133,792	103,786	(30,006)	-22.4%
Direct Cost of Distribution	8210	5,358	10,693	5,998	(4,695)	-43.9%
Royalties	8220	2,812	3,922	1,754	(2,168)	-55.3%
Contribution I	8300	102,134	114,798	99,832	(14,966)	-13.0%
Direct Promotion Cost	8320	886	1,032	609	(423)	-41.0%
Cost of Samples	8340	-	-	-	-	-
Contribution IA	8500	101,248	113,766	99,223	(14,543)	-12.8%
Own Field Force	8502	1,809	2,538	2,436	(102)	-4.0%
Rented Field Force	8503	-	-	-	-	-
Commission Co-Promotion	8504	-	-	-	-	-
Contribution II	8505	99,439	111,228	96,787	(14,441)	-13.0%
General Promotion - Activities	8510	-	-	-	-	-
Marketing & Sales Organization	8520	3,269	3,456	3,581	125	3.6%
Indirect Cost of Distribution	8540	13,228	10,619	38,616	27,997	263.7%
Research & Development I	8550	16,305	21,848	21,624	(224)	-1.0%
Medicine I	8560	12,487	17,442	13,972	(3,470)	-19.9%
Administration Cost	8610	6,067	3,623	1,976	(1,647)	-45.5%
Variance Cost of Goods	8629	27	-	224	224	100.0%
Variance from Other Internal Service (	8630	(247)	-	-	-	-
(Income)/Expense I	8640	355	439	(477)	(916)	-208.7%
Contribution III	8700	47,948	53,801	17,271	(36,530)	-67.9%
Marketing II	8733	-	-	-	-	-
Process Development	8735	2,791	2,447	5,166	2,719	111.1%
Cost of Idle Capacity	8738	-	-	-	-	-
Variances Production	8739	2,768	-	(1,166)	(1,166)	-100.0%
(Income)/Expense II	8742	-	(6,032)	(10,296)	(4,264)	70.7%
Other Expenses in Production	8743	3,187	4,859	4,628	(231)	-4.8%
Contribution IV	8755	39,202	52,527	18,939	(33,588)	-63.9%

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**PNR 8200: Standard Cost of Goods Sold**

- Down \$30.0 Million
  - Due to the decrease in the Net Sales of Multisource products. Also, a favorable product mix reduced the CoGS as a percent of Net Sales from 50.8% to 49.1%.

**PNR 8210: Direct Cost of Distribution**

- Down \$4.7 Million
  - Due primarily to the decrease in Net Sales units from 21.6 Million units to 15.0 Million units.

**PNR 8220: Royalties**

- Down \$2.2 Million
  - Delayed launch of Clonidine (down \$1.4 Million).
  - Lorazepam returns reserve was increased reducing Net Sales, therefore reducing Royalties (down \$0.5 Million).
  - Reduced Ipratropium Bromide Nasal sales (down \$0.2 Million).

**PNR 8540: Indirect Cost of Distribution**

- Up \$28.0 Million
  - Increased obsolescence provision for Fluticasone Bright Stock (\$15.0 Million).
  - Increased obsolescence provision for Fluticasone API (\$5.8 Million).
  - Increase in Product Destructuations, Provisions for Obsolescence, and Product Donations of \$4.7 Million all related to short dated or out of code products.
  - Remaining difference related to warehousing expense pertaining to third party fees for product destructuations and capital project expenses.

**PNR 8560: Medicine I**

- Down \$3.5 Million
  - Clinical Trial Expense down \$3.1 Million.

**PNR 8610: Administration**

- Down \$1.6 Million
  - Savings of \$1.1 Million in IT (for more details see the IT section).
  - Savings of \$0.4 Million in HR.
  - Due to methodology all savings are reflected in the Multisource P&L.

**PNR 8640: Income / Expense I**

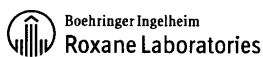
- \$0.9 Million favorable
  - Due primarily to \$0.6 Million of income from the sale of remaining UDV assets (40% of total income received. Remainder reported on Affiliate P&L)

**PNR 8735: Process Development**

- Up \$2.7 Million due primarily to change in methodology
  - Budget 2004 reflected process development work attributed to the Affiliate Business, which has been changed to be 100% Multisource since the work is all Multisource related.

**PNR 8739: Variances Production**

- Favorable \$1.2 Million
  - Favorable standard volume variance (down \$6.1 Million).
  - Unfavorable overhead costs (up \$4.3 Million).



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**ROXANE LABORATORIES, INC.**  
**INCOME STATEMENT**  
**PRESCRIPTION MEDICINE**  
**Multisource**  
**Year End 2004 vs. Budget 2004**

Thousands U.S.\$

		Year End	Budget	Year End	Year End 2004 Over (Under) Budget 2004	Variance %
	PNR	2003	2004	2004		
Gross Sales of Goods	8030	323,790	788,197	388,568	(399,629)	-50.7%
Sales Discounts	8050	110,104	524,992	177,198	(347,794)	-66.2%
Product Net Sales		213,686	263,205	211,371	(51,834)	-19.7%
Royalty Income	8080	-	-	-	-	-
Other Income	8090	-	-	-	-	-
Net Sales	8100	213,686	263,205	211,370	(51,835)	-19.7%
Standard Cost of Goods Sold	8200	103,382	133,792	103,786	(30,006)	-22.4%
Direct Cost of Distribution	8210	5,358	10,693	5,998	(4,695)	-43.9%
Royalties	8220	2,812	3,922	1,754	(2,168)	-55.3%
Contribution I	8300	102,134	114,798	99,832	(14,966)	-13.0%
Direct Promotion Cost	8320	886	1,032	609	(423)	-41.0%
Cost of Samples	8340	-	-	-	-	-
Contribution IA	8500	101,248	113,766	99,223	(14,543)	-12.8%
Own Field Force	8502	1,809	2,538	2,436	(102)	-4.0%
Rented Field Force	8503	-	-	-	-	-
Commission Co-Promotion	8504	-	-	-	-	-
Contribution II	8505	99,439	111,228	96,787	(14,441)	-13.0%
General Promotion - Activities	8510	-	-	-	-	-
Marketing & Sales Organization	8520	3,269	3,456	3,581	125	3.6%
Indirect Cost of Distribution	8540	13,228	10,619	38,616	27,997	263.7%
Research & Development I	8550	16,305	21,848	21,624	(224)	-1.0%
Medicine I	8560	12,487	17,442	13,972	(3,470)	-19.9%
Administration Cost	8610	6,067	3,623	1,976	(1,647)	-45.5%
Variance Cost of Goods	8629	27	-	224	224	100.0%
Variance from Other Internal Service (	8630	(247)	-	-	-	-
(Income)/Expense I	8640	355	439	(477)	(916)	-208.7%
Contribution III	8700	47,948	53,801	17,271	(36,530)	-67.9%
Marketing II	8733	-	-	-	-	-
Process Development	8735	2,791	2,447	5,166	2,719	111.1%
Cost of Idle Capacity	8738	-	-	-	-	-
Variances Production	8739	2,768	-	(1,166)	(1,166)	-100.0%
(Income)/Expense II	8742	-	(6,032)	(10,296)	(4,264)	70.7%
Other Expenses in Production	8743	3,187	4,859	4,628	(231)	-4.8%
Contribution IV	8755	39,202	52,527	18,939	(33,588)	-63.9%

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**PNR 8742: Income / Expense II**

- Favorable \$4.3 Million
  - Favorable accrual reversal for Elan Back Order Penalty (\$4.0 Million).



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**ROXANE LABORATORIES, INC.**  
**INCOME STATEMENT**  
**THIRD PARTY MANUFACTURING**  
**Toll & Outlicensing**  
**Year End 2004 vs. Budget 2004**

Thousands U.S.\$

		Year End	Budget	Year End	Year End 2004	Variance
	PNR	2003	2004	2004	Over (Under) Budget 2004	%
Gross Sales of Goods	8030	3,735	4,817	4,928	111	2.3%
Sales Discounts	8050	1,411	-	-	-	-
Product Net Sales		2,324	4,817	4,928	111	2.3%
Royalty Income	8080	362	241	422	181	75.1%
Other Income	8090	16,029	5,455	9,975	4,520	82.9%
Net Sales	8100	18,715	10,513	15,325	4,812	45.8%
Standard Cost of Goods Sold	8200	17,005	10,683	15,064	4,381	41.0%
Direct Cost of Distribution	8210	69	213	-	(213)	-100.0%
Royalties	8220	-	-	-	-	-
Contribution I	8300	1,641	(383)	261	644	-168.1%
Direct Promotion Cost	8320	-	-	-	-	-
Cost of Free Goods	8340	-	-	-	-	-
Contribution IA	8500	1,641	(383)	261	644	-168.1%
Own Field Force	8502	-	-	-	-	-
Rented Field Force	8503	-	-	-	-	-
Commission Co-Promotion	8504	-	-	-	-	-
Contribution II	8505	1,641	(383)	261	644	-168.1%
General Promotion - Activities	8510	-	-	-	-	-
Marketing & Sales Organization	8520	-	-	-	-	-
Indirect Cost of Distribution	8540	1,180	748	1,792	1,044	139.6%
Research & Development I	8550	897	-	-	-	-
Medicine I	8560	481	562	453	(109)	-19.4%
Administration Cost	8610	211	290	286	(4)	-1.4%
Variance Cost of Goods	8629	-	-	-	-	-
Variance from Other Internal Service Chgs	8630	(32)	-	-	-	-
(Income)/Expense I	8640	881	781	2,316	1,535	196.5%
Contribution III	8700	(1,977)	(2,764)	(4,586)	(1,822)	65.9%
Marketing II	8733	-	-	-	-	-
Process Development	8735	-	-	-	-	-
Cost of Idle Capacity	8738	-	-	-	-	-
Variances Production	8739	1,319	-	423	423	100.0%
(Income)/Expense II	8742	(954)	(1,000)	(1,036)	(36)	3.6%
Other Expenses In Production	8743	260	721	101	(620)	-86.0%
Contribution IV	8755	(2,602)	(2,485)	(4,074)	(1,589)	63.9%



Actual 2004

## 2.2. 6E - Third Party Manufacturing (aaiPharma & Cebert)

The Third Party Manufacturing P&L reflects revenue and expense line items pertaining to the divestiture of the Pain/Palliative products to aaiPharma which include Duraclon, Oramorph, Roxanol and Roxicodone as well as the products Outlicensed to Cebert, which pertain to the Methadone family.

### **PNR 8100: Net Sales**

- Up \$4.8 Million.
  - Increase is due to the aaiPharma products Oramorph, up \$3.0 Million, and Roxicodone, up \$2.1 Million while Roxanol had a decrease of \$0.8 Million.

### **PNR 8200: Standard Cost of Goods Sold**

- Up \$4.4 Million
  - Due to the increase in the respective Net Sales of aaiPharma products.

### **PNR 8540: Indirect Cost of Distribution**

- Up \$1.0 Million
  - Increase in Provisions for Obsolescence due to unstable financial position of aaiPharma.

### **PNR 8640: Income / Expense I:**

- Up \$1.5 Million
  - Bad debt expenses for aaiPharma of \$1.5 Million due to unstable financial position.

### **PNR 8743: Other Expenses in Production**

- Down \$0.6 Million
  - Lower product related destructions



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<b>ROXANE LABORATORIES, INC.</b> <b>INCOME STATEMENT</b> <b>AFFILIATES</b> <b>Year End 2004 vs. Budget 2004</b>						
Thousands U.S.\$						
	PNR	Year End 2003	Budget 2004	Year End 2004	Year End 2004 Over (Under) Budget 2004	Variance %
Gross Sales of Goods	8030	287,586	202,523	307,474	104,951	51.8%
Sales Discounts	8050	-	-	-	-	-
Net Sales of Goods		287,586	202,523	307,474	104,951	51.8%
Royalty Income	8080	-	-	-	-	-
Other Income	8090	-	-	1,789	1,789	100.0%
Net Sales	8100	287,586	202,523	309,263	106,740	52.7%
Standard Cost of Goods Sold	8200	281,366	197,144	301,699	104,555	53.0%
Direct Cost of Distribution	8210	-	-	-	-	-
Royalties	8220	-	-	-	-	-
Contribution I	8300	6,220	5,379	7,564	2,185	40.6%
Direct Promotion Costs	8320	-	-	-	-	-
Cost of Free Goods & Samples	8340	-	-	-	-	-
Contribution IA	8500	6,220	5,379	7,564	2,185	40.6%
Own Field Force	8502	28	-	-	-	-
Rented Field Force	8503	-	-	-	-	-
Commission Co-Promotion	8504	-	-	-	-	-
Contribution II	8505	6,192	5,379	7,564	2,185	40.6%
General Promotion - Activities	8510	-	-	-	-	-
Marketing & Sales Organization	8520	-	-	-	-	-
Indirect Cost of Distribution	8540	958	1,608	1,925	317	19.7%
Research & Development I	8550	-	-	-	-	-
Medicine I	8560	(85)	200	(226)	(426)	-213.0%
Administration Cost	8610	4,536	5,579	5,743	164	2.9%
Variance Cost of Goods	8629	(88)	-	(56)	(56)	-100.0%
Variance from Other Internal Service Chg	8630	(622)	-	-	-	-
(Income)/Expense I	8640	1,119	675	4,485	3,810	564.4%
Contribution III	8700	374	(2,683)	(4,307)	(1,624)	60.5%
Marketing II	8733	-	-	-	-	-
Process Development	8735	869	1,632	46	(1,586)	-97.2%
Cost of Reserved Capacity	8737	-	7,725	11,362	3,637	47.1%
Cost of Idle Capacity	8738	5,245	5,930	5,371	(559)	-9.4%
Variances Production	8739	898	(136)	(1,009)	(873)	641.9%
(Income)/Expense II	8742	-	-	(26,388)	(26,388)	-100.0%
Other Expenses In Production	8743	6,003	2,012	10,239	8,227	408.9%
Contribution IV	8755	(12,641)	(19,846)	(3,928)	15,918	-80.2%

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**2.3. 6G – Affiliates****PNR 8100: Net Sales**

- Up \$106.7 Million
  - Following transfer of packaging of Mobic to Mexico, Mexico was unable to meet full demand, especially following the withdrawal of VIOXX from the market, this accounts for an increase of \$117.2 Million in Sales.
  - Increase of \$7.9 Million in Sales of Catapress TTS due to lack of Generic competition.
  - Increase of \$4.7 Million in Sales of Viramune
  - Partially offset by a decrease of \$10.1 Million in Sales of Atrovent following launch of Spiriva.
  - Partially offset by a decrease of \$13.7 Million in Sales of Spiriva.

**PNR 8200: Standard Cost of Goods Sold**

- Up \$104.6 Million
  - Increase is attributable to the increase in Net Sales noted above.

**PNR 8610: Administration**

- Up \$0.2 Million
  - Due to methodology all savings are reflected in the Multisource P&L.

**PNR 8640: Income / Expense I:**

- Up \$3.8 Million
  - One time charge of \$4.1 Million for the disposal (write off) of Spiriva Robots due to changes in the U.S. packaging configurations.
  - \$0.7 Million due to miscellaneous fixed asset disposals.
  - Partially offset by \$0.9 Million of income from the sale of remaining UDV assets (60% of total income received. Remainder reported on Multisource P&L)

**PNR 8735: Process Development**

- Down \$1.6 Million due to change in methodology.
  - Budget 2004 reflects process development work attributed to the Affiliate Business, which has been changed to be 100% Multisource since the work is all Multisource related.

**PNR 8737: Cost of Reserve Capacity**

- Up \$3.6 Million
  - Lower production volumes for the Spiriva Export business.

**PNR 8738: Cost of Idle Capacity**

- Down \$0.6 Million
  - Higher utilization due to increased Affiliate business, primarily Mobic.

**PNR 8739: Variances Production**

- Down \$0.9 Million
  - Favorable destructions.
  - Favorable Mobic absorption and production variances.
  - Unfavorable Spiriva absorption and production variances.



Actual 2004

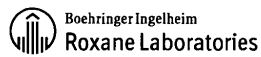
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Gross Sales of Goods	8030	287,586	202,523	307,474	104,951	51.8%
Sales Discounts	8050	-	-	-	-	-
Net Sales of Goods		287,586	202,523	307,474	104,951	51.8%
Royalty Income	8080	-	-	-	-	-
Other Income	8090	-	-	1,789	1,789	100.0%
Net Sales	8100	287,586	202,523	309,263	106,740	52.7%
Standard Cost of Goods Sold	8200	281,366	197,144	301,699	104,555	53.0%
Direct Cost of Distribution	8210	-	-	-	-	-
Royalties	8220	-	-	-	-	-
Contribution I	8300	6,220	5,379	7,564	2,185	40.6%
Direct Promotion Costs	8320	-	-	-	-	-
Cost of Free Goods & Samples	8340	-	-	-	-	-
Contribution IA	8500	6,220	5,379	7,564	2,185	40.6%
Own Field Force	8502	28	-	-	-	-
Rented Field Force	8503	-	-	-	-	-
Commission Co-Promotion	8504	-	-	-	-	-
Contribution II	8505	6,192	5,379	7,564	2,185	40.6%
General Promotion - Activities	8510	-	-	-	-	-
Marketing & Sales Organization	8520	-	-	-	-	-
Indirect Cost of Distribution	8540	958	1,608	1,925	317	19.7%
Research & Development I	8550	-	-	-	-	-
Medicine I	8560	(85)	200	(226)	(426)	-213.0%
Administration Cost	8610	4,536	5,579	5,743	164	2.9%
Variance Cost of Goods	8629	(88)	-	(56)	(56)	-100.0%
Variance from Other Internal Service Chg	8630	(622)	-	-	-	-
(Income)/Expense I	8640	1,119	675	4,485	3,810	564.4%
Contribution III	8700	374	(2,683)	(4,307)	(1,624)	60.5%
Marketing II	8733	-	-	-	-	-
Process Development	8735	869	1,632	46	(1,586)	-97.2%
Cost of Reserved Capacity	8737	-	7,725	11,362	3,637	47.1%
Cost of Idle Capacity	8738	5,245	5,930	5,371	(559)	-9.4%
Variances Production	8739	898	(136)	(1,009)	(873)	641.9%
(Income)/Expense II	8742	-	-	(26,388)	(26,388)	-100.0%
Other Expenses In Production	8743	6,003	2,012	10,239	8,227	408.9%
Contribution IV	8755	(12,641)	(19,846)	(3,928)	15,918	-80.2%

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**PNR 8742: Income / Expense II:**

- Up \$26.4 million
  - \$4.0 Million in reimbursement for the Spiriva Project.
  - \$13.0 Million in reimbursement of Cost of Reserve Capacity and Idle Capacity for Spiriva.
  - \$9.4 Million in reimbursement of Spiriva Project costs

**PNR 8743: Other Expenses in Production**

- Up \$8.2 Million
  - Spiriva Project Expenses are no longer charged back to BIPI as reflected in the 2004 Budget due to the Toll Manufacturing Agreement that now exists between BII and RLI. This was offset as part of the \$26.4 Million reimbursement from BII.



Actual 2004

**ROXANE LABORATORIES, INC.**  
**INCOME STATEMENT**  
**AFFILIATES BII (TMA)**  
**Year End 2004 vs. Budget 2004**

Thousands U.S.\$

	PNR	Budget 2004	Year End 2004	Year End 2004 Over (Under) Budget 2004	Variance %
Gross Sales of Goods	8030	-	-	-	-
Sales Discounts	8050	-	-	-	-
Net Sales of Goods		-	-	-	-
Royalty Income	8080	-	-	-	-
Other Income	8090	15,289	1,729	(13,560)	-88.7%
Net Sales	8100	15,289	1,729	(13,560)	-88.7%
Standard Cost of Goods Sold	8200	13,900	1,573	(12,327)	-88.7%
Direct Cost of Distribution	8210	-	-	-	-
Royalties	8220	-	-	-	-
Contribution I	8300	1,389	156	(1,233)	-88.8%
Direct Promotion Costs	8320	-	-	-	-
Cost of Free Goods & Samples	8340	-	-	-	-
Contribution IA	8500	1,389	156	(1,233)	-88.8%
Own Field Force	8502	-	-	-	-
Rented Field Force	8503	-	-	-	-
Commission Co-Promotion	8504	-	-	-	-
Contribution II	8505	1,389	156	(1,233)	-88.8%
General Promotion - Activities	8510	-	-	-	-
Marketing & Sales Organization	8520	-	-	-	-
Indirect Cost of Distribution	8540	-	-	-	-
Research & Development I	8550	-	-	-	-
Medicine I	8560	-	-	-	-
Administration Cost	8610	-	-	-	-
Variance Cost of Goods	8629	-	-	-	-
Variance from Other Internal Service Chg	8630	-	-	-	-
(Income)/Expense I	8640	-	4,074	4,074	100.0%
Contribution III	8700	1,389	(3,918)	(5,307)	-382.1%

## TMA related cost positions

Cost of Reserve Capacity	8737	7,725	11,362	3,637	47.1%
Cost of Idle Capacity	8738	1,497	1,726	229	15.3%
(Income)/Expense II (reimbursement)	8742	-	(26,388)	(26,388)	-100.0%
Other Expenses in Production	8743	-	9,066	9,066	100.0%
Contribution IV	8755	(7,833)	316	8,149	-104.0%

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Actual 2004

### 2.3.1. Affiliates BII (TMA)

The Affiliates BII (TMA) P&L reflects revenue and expense line items pertaining directly to the Toll Manufacturing Agreement between BII and Roxane Laboratories. Under this agreement products of the Spiriva and Tipranavir family will be packaged / manufactured by RLI and sold directly to BII without the intermediation of BIPI. BII provides API as part of the contract free of charge.

#### Important information:

- TMA started in April 2004.
- In 2004, RLI only packages Spiriva products.
- The markup for these products according to the agreement is 10% of conversion costs.

#### **PNR 8100: Net Sales**

- Down \$13.6 Million
  - Lower volume manufactured, due to changes in demand from BII.

#### **PNR 8200: Standard Cost of Goods Sold**

- Down \$12.3 Million
  - Reflects the decrease in units produced.

#### **PNR 8640: Income / Expense I:**

- Down \$4.1 Million.
  - One time charge of \$4.1 Million for the disposal (write off) of the Spiriva Robots in December 2004 due to a change in the U.S. packaging configurations.

#### **PNR 8737: Cost of Reserved Capacity**

- Up \$3.6 Million
  - Due to lower than budgeted Spiriva unit volume.

#### **PNR 8742: Income / Expense II**

- Up \$26.4 Million
  - \$13.0 Million in reimbursement of Cost of Reserve Capacity and Idle Capacity related to the production of Spiriva and Tipranavir according to the agreement.
  - Reimbursement of \$4.0 Million in consideration of RLI's commitment to make its facility and personnel available for the manufacture of drug products.
  - Reimbursement of \$9.4 Million in project related expenses for Spiriva

#### **PNR 8743: Other Expenses in Production:**

- Up \$9.1 Million.
  - This line item consists of Spiriva Project Expenses that are no longer charged to BIPI due to the Toll Manufacturing Agreement between RLI and BII. These expenses were previously recorded on BIPI books and now remain on RLI books.



Actual 2004



Actual 2004

### **3. Manufacturing Pharma**

The Columbus packaged volume for year end is approximately 49.7 million units, representing a 10% decrease from Budget 2004 of 54.9 million units. The overall decrease in packaged units is driven primarily by the reduction of MDI units resulting from the Spiriva launch. Fully manufactured units are down 0.6% due to lower than budgeted Spiriva volumes. Multisource production volume is down 25.1% due to delayed launch of Fluticasone and Clonidine. In addition aaiPharma is down 5.1% and Ceberit was up 42.9%, versus the original Budget 2004.

Columbus Production spending in 2004 is \$77.7 Million, or \$5.2 million below Budget 2004 due to the following factors:

- Salary Expenses are lower due to lower than planned headcount which is a direct result of the lower Spiriva and Fluticasone volumes.
- Social costs are \$1.0 Million unfavorable due to increased number of employees that have become fully vested after having achieved 5 years of service with the company following the hiring that took place as part of the OPINA project.
- Positive absorption and efficiency improvements attributed \$5.3 Million in favorable variances.



Actual 2004

**4. Human Resources - HR**

<b>ROXANE LABORATORIES, INC</b> <b>Headcount</b> <b>Actual 2004</b>				
	Actual 2003	Budget 2004	Actual 2004	Actual 2004 Over(Under) Budget 2004
Pharmaceutical Manufacturing	752	827	765	(62)
Marketing Office	-	-	-	-
Marketing Field	-	-	-	-
Medicine Human Pharmaceutical	29	35	31	(4)
R&D Human Pharmaceutical	61	72	70	(2)
Central Functions	69	77	66	(11)
<b>Total Headcount</b>	<b>911</b>	<b>1,011</b>	<b>932</b>	<b>(79)</b>

**Regular Headcount**

- Down 79 positions.
  - Medicine, R&D, and Central Functions had taken down their headcount by 17, 14 are attributable to the cost cutting measures requested by Headquarters and 3 are due to departmental turnover.
  - Pharmaceutical Mfg also cut their headcount by 34 to comply with the cost cutting measures, furthermore the delayed launch of Fluticasone and Clonidine coupled with the reduction of packaged MDI units resulting from the Spiriva launch led to an additional reduction of 28 headcounts reduction.



Actual 2004

<b>ROXANE LABORATORIES, INC</b> <b>PERSONNEL COSTS</b> <b>Actual 2004</b> <b>Thousands U.S.\$</b>			
	<b>Actual 2003</b>	<b>Budget 2004</b>	<b>Actual 2004</b>
<b>Personnel Costs</b>	<b>70,196</b>	<b>77,903</b>	<b>73,927</b>
<b>Restructuring</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Total Personnel Costs</b>	<b>70,196</b>	<b>77,903</b>	<b>73,927</b>
<b>Pers. Costs (Excl. Restructuring) as a % of Net Sales</b>	<b>13.55 %</b>	<b>16.36 %</b>	<b>13.79 %</b>
<b>Total Headcount</b>	<b>911</b>	<b>1,011</b>	<b>932</b>

**Personnel Costs**

- Down \$4 Million
  - Due primarily to decrease in Salaries/Wages, which is a direct result of the actual 2004 headcount being 79 headcount less than Budget 2004.



Boehringer Ingelheim  
Roxane Laboratories

Actual 2004

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Boehringer Ingelheim  
Roxane Laboratories

Actual 2004

## **5. Information Technology - IT**

- IT costs reflect a \$1.1 million decrease to 2004 Budget
  - \$0.2 Million decrease due to the transfer of 4 people transferring from IT into the Facilities area.
  - \$0.3 Million decrease in external services for the new IT Data Center construction and infrastructure cabling spending delayed until 2005.
  - \$0.1 Million decrease in communication costs due to credits received for MCI telephone charges and less than anticipated number of Secure ID tokens for remote access.
  - \$0.2 Million decrease in hardware/software maintenance costs due to contracts not renewed for Bindview, EMC, and other Server support.
  - \$0.2 Million decrease in depreciation due to timing of IT projects.



Actual 2004

<b>ROXANE LABORATORIES</b> <b>INCOME STATEMENT</b> <b>TOTAL COMPANY</b> <b>Year End 2004 vs. Budget 2004</b>						
Thousands U.S.\$						
		Year End	Budget	Year End	Year End 2004	
	PNR	2003	2004	2004	Over (Under)	Variance
					Budget 2004	%
Gross Sales of Goods	8030	616,598	995,537	700,970	(294,567)	-29.6%
Sales Discounts	8050	114,754	524,992	177,198	(347,794)	-66.2%
Product Net Sales		501,844	470,545	523,773	53,228	11.3%
Royalty Income	8080	362	241	422	181	75.1%
Other Income	8090	16,029	5,455	11,764	6,309	115.7%
Net Sales	8100	518,235	476,241	535,958	59,717	12.5%
Standard Cost of Goods Sold	8200	402,241	341,619	420,549	78,930	23.1%
Direct Cost of Distribution	8210	5,506	10,906	5,998	(4,908)	-45.0%
Royalties	8220	2,799	3,922	1,754	(2,168)	-55.3%
Contribution I	8300	107,689	119,794	107,657	(12,137)	-10.1%
Direct Promotion Cost	8320	886	1,032	609	(423)	-41.0%
Cost of Free Goods & Samples	8340	-	-	-	-	-
Contribution IA	8500	106,803	118,762	107,048	(11,714)	-9.9%
Own Field Force	8502	1,838	2,538	2,436	(102)	-4.0%
Rented Field Force	8503	-	-	-	-	-
Commission Co-Promotion	8504	-	-	-	-	-
Contribution II	8505	104,965	116,224	104,612	(11,612)	-10.0%
General Promotion - Activities	8510	1	-	-	-	-
Marketing & Sales Organization	8520	3,286	3,456	3,581	125	3.6%
Indirect Cost of Distribution	8540	16,730	12,975	42,333	29,358	226.3%
Research & Development I	8550	17,202	21,848	21,624	(224)	-1.0%
Medicine I	8560	12,883	18,204	14,199	(4,005)	-22.0%
Administration Cost	8610	10,898	9,492	8,005	(1,487)	-15.7%
Variance Cost of Goods	8629	(61)	-	168	168	100.0%
Variance from Other Internal Service Chgs	8630	(901)	-	-	-	-
(Income)/Expense I	8640	(9,351)	1,895	6,324	4,429	233.7%
Contribution III	8700	54,279	48,354	8,378	(39,976)	-82.7%
Marketing II	8733	-	-	-	-	-
Process Development	8735	3,660	4,079	5,212	1,133	27.8%
Cost of Reserved Capacity	8737	-	7,725	11,362	3,637	47.1%
Cost of Idle Capacity	8738	5,245	5,930	5,371	(559)	-9.4%
Variances Production	8739	4,958	(136)	(1,752)	(1,616)	1188.2%
(Income)/Expense II	8742	(954)	(12,732)	(37,720)	(24,988)	196.3%
Other Expenses In Production	8743	9,461	7,592	14,968	7,376	97.2%
Contribution IV	8755	31,908	35,896	10,937	(24,959)	-69.5%
Research & Development II	8756	326	-	-	-	-
Medicine II	8757	211	-	-	-	-
(Income)/Expense III	8762	162	243	253	10	4.1%
Operating Income/(Loss) BA	8800	31,209	35,653	10,684	(24,969)	-70.0%
Financial (Income)/Expense	8810	771	2,108	3,234	1,126	53.4%
Income/(Loss) Before Taxes	8900	30,438	33,545	7,450	(26,095)	-77.8%
Taxes	8910	11,169	13,083	2,130	(10,953)	-83.7%
Income/(Loss) After Taxes	8990	19,269	20,462	5,320	(15,142)	-74.0%

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## 6. Finance

### 6.1. Consolidated Income Statement

#### Business Overview – Year End 2004

##### **Prescription Medicine (Multisource) Summary (Net Sales & Contribution IV)**

- PNR 8100 – Net Sales decreased by \$51.8 Million.
  - Fluticasone, Clonidine and Fluconazole down \$66.7 Million due to delayed launch.
  - Megesterol up \$14.5 Million primarily due to less price erosion than anticipated.
  - Roxicet up \$11.1 Million primarily due to increased unit sales.
- PNR 8755 – Contribution IV decreased by \$33.6 Million.
  - Indirect Cost of Distribution increased by \$28 Million due primarily to obsolescence provisions and destructions.
  - Lower sales.

##### **Third Party Manufacturing Summary (Net Sales & Contribution IV)**

- PNR 8100 – Net Sales increase by \$4.8 Million.
  - Increase of \$3.0 Million in aaiPahrma product Oramorph and \$2.1 Million in Roxicodone.
- PNR 8755 – Contribution IV is expected to fall by \$1.6 Million.
  - Primarily due to bad debt expense of \$1.5 Million for aaiPharma.

##### **Affiliates Summary (Net Sales & Contribution IV)**

- PNR 8100 – Net Sales increased \$106.7 Million.
  - Primarily due to the not realized Mobic production transfer to Mexico.
- PNR 8755 – Contribution IV increased \$15.9 Million.
  - Primarily due to Spiriva Project reimbursements.
  - Partially offset by higher Cost of Reserved Capacity and Other Expenses in Production.

##### **RLI Legal Entity (Contribution IV & Income after Taxes)**

- PNR 8755 – Contribution IV & PNR 8800 – Operating Income decreased \$25 Million
  - Primarily due to higher expenses in Indirect Cost of Distribution, Income / Expenses I above Contribution III.
  - Primarily due to higher expenses in Cost of Reserve Capacity and Other Expenses in Production.
  - Partially offset by a reimbursement from BII shown in Income / Expense II, related to Cost of Reserved Capacity reimbursement for Spiriva according to the TMA.
- PNR 8810 – Financial Income / Expense increased by \$1.1 Million.
  - Primarily due to an increase in Cash Expenses
- PNR 8890 – Operating Income decreased by \$15.1 Million.



Actual 2004



Actual 2004

**6.2. Capital Expenditure**

The RLI 2004 Budget was \$63.5 Million. The 2004 Actual is \$54.6 Million, or 86% of the total budget. The reduced spending of \$8.9 Million is mainly due to project delays and cancellations.

Function	2004 Bud	2004 Act	Variance
CBMD	\$2,822	\$1,061	-\$1,761
R&D	\$871	\$665	-\$206
Mfg. Pharma	58,937	\$50,624	-\$8,313
Infrastructure	\$850	\$2,210	\$1,360
<b>Total</b>	<b>\$63,481</b>	<b>\$54,560</b>	<b>-\$8,921</b>

Major projects that contributed to this decreased spending are as follows:

No.	Name	2004 Bud	2004 Act	Variance	Comment
095	Thermoformers (S15)	4,800	1,195	-3,605	Implementation delays
106	East Solids Mfg Upgrade	1,344	3,388	2,044	Carry-over from 2003
117	Liquids Mfg Safety Upgrades	5,500	7,924	2,424	Project accelerated from 2005
119	Spiriva - Phase B (CC#485447)	24,949	26,880	1,931	Impact of exchange rate fluctuations
142	Oak Street Plant	2,750	150	-2,600	Delay - lack of scope definition
146	IT Data Center	1,440	16	1,424	Implementation delays
171	SO3 Upgrades	1,350	0	-1,350	Cancelled



Actual 2004

ROXANE LABORATORIES, INC. BALANCE SHEET Year End 2004 vs. Budget 2004					
Thousands U.S.\$					
	PNR	Actual 2003	Budget 2004	Year End 2004	Year End 2003 Over (Under) Budget 2003
<b>ASSETS</b>					
Intangible Assets	1090	4,206	3,459	3,459	-
Property, Plant and Equipment	1190	137,997	185,501	163,009	(22,492)
Long-term Investments	1290	43	10	43	33
Total Prop, Plant, Equip, and Invest	1300	142,246	188,970	166,511	(22,459)
Inventories	1390	109,543	107,137	115,607	8,470
Trade Accounts Receivable 3rd Parties	1400	37,055	120,279	56,378	(63,901)
Trade Accounts Receivable fr. Affil. Comp.	1410	-	-	-	-
Short-Term advances to Affiliates	1420	-	-	-	-
Other Assets	1500	9,738	25,242	3,446	(21,796)
Deferred Tax Assets	1510	33,915	25,000	51,370	26,370
Total Receivables	1590	80,708	170,521	111,194	(59,327)
Liquid Funds	1790	-	-	-	-
Prepaid Expenses a.o. deferred items	1890	343	125	439	314
Total Current Assets	1900	190,594	277,783	227,240	(50,543)
Total Assets	1000	332,840	466,753	393,751	(73,002)
<b>SHAREHOLDERS' EQUITY, PROVISIONS, AND LIABILITIES</b>					
Share Capital	2010	19	19	19	-
Additional Paid-In Capital	2020	8,735	8,735	8,735	-
Retained Earnings, Opening Balance	2200	46,121	60,599	46,121	(14,478)
Interim Dividends	2207	-	-	-	-
Net Income (Loss), Current Period	2210	19,269	20,462	5,320	(15,142)
Total Shareholders' Equity	2300	74,144	89,815	60,195	(29,620)
Provision for Pensions	2410	17,195	24,000	21,102	(2,898)
Tax Provisions	2450	59,924	17,000	34,166	17,166
Deferred Tax Prov/Liabilities	2470	12,837	-	18,025	18,025
Other Provisions and Accruals	2500	70,466	73,024	71,975	(1,049)
Total Provisions	2600	160,422	114,024	145,268	31,244
Trade Accounts Payable	2610	19,591	48,776	24,761	(24,015)
Payable to Banks	2630	-	-	-	-
Payables to Affiliates	2720	6,650	9,000	71,428	62,428
Loans from Affiliates	2740	62,342	204,388	88,721	(115,667)
Other Liabilities	2820	87	750	153	(597)
Total Liabilities	2900	88,670	262,914	185,063	(77,851)
Deferred Income	2950	9,604	-	3,225	3,225
Total Liabilities and Provisions	2990	258,696	376,938	333,556	(43,382)
Total Equity, Liabilities and Provisions	2000	332,840	466,753	393,751	(73,002)



Actual 2004

**6.3. Balance Sheet****PNR 1300: Property, Plant and & Equipment**

- Down \$22.4 Million.
  - Year-end 2003 was \$7.8 Million lower than anticipated in Budget 2004.
  - Capital expenditures were reduced in 2004 mainly due to project delays and cancellations.

**PNR 1390: Inventories**

- Up \$8.5 Million
  - Due primarily to \$22 Million of Mobic bulk that was in transit at year end to support the increased sales forecast that resulted from the Vioxx withdrawal.
  - Partially offset by inventory reserves established to cover potential dating issues with Fluticazone inventory.

**PNR 1400: Trade Accounts Receivables –3rd Parties**

- Down \$63.9 Million.
  - Reflects the effort being made to reduce the number of days of sales outstanding, which has already been reduced from 61 to 47 days.

**PNR 1500: Other Assets**

- Down \$21.8 Million.
  - Due primarily to the elimination of the Elan receivables (\$25 Million) when aai Pharma purchased its product lines.

**PNR 1510: Deferred Tax Assets & PNR 2470 Deferred Tax Prov/Liab**

- Up \$8.3 Million.
  - The budgeted number for 2004 is a combination of Deferred Tax Asset and Deferred Tax Liability.
  - Increases in Pension reserves and Chargeback reserves.

**PNR 2200: Retained Earnings, Opening Balance**

- Down \$14.5 Million.
  - In 2004 RLI paid an Interim Dividend of \$ 19.3 Million to BIC.

**PNR 2410: Provision for Pensions**

- Down \$2.9 Million.
  - Lowered due to funding in 2004.

**PNR 2450 Tax Provisions**

- Up \$17.2 Million.
  - Due to higher balances in Tax Provision accounts at the year end.

**PNR 2500: Other Provisions and Accruals**

- Down \$1.0 Million.
  - Closed out UDV reserve and reclassified \$1.5Million to Income / Expense I.

**PNR 2610: Trade Accounts Payable**

- Down \$24.0 Million.
  - Revised down to be in accordance to current balances.



Actual 2004

ROXANE LABORATORIES, INC. BALANCE SHEET Year End 2004 vs. Budget 2004					
Thousands U.S.\$					
	PNR	Actual 2003	Budget 2004	Year End 2004	Year End 2003 Over (Under) Budget 2003
<b>ASSETS</b>					
Intangible Assets	1090	4,206	3,459	3,459	-
Property, Plant and Equipment	1190	137,997	185,501	163,009	(22,492)
Long-term Investments	1290	43	10	43	33
Total Prop, Plant, Equip, and Invest	1300	142,246	188,970	166,511	(22,459)
Inventories	1390	109,543	107,137	115,607	8,470
Trade Accounts Receivable 3rd Parties	1400	37,055	120,279	56,378	(63,901)
Trade Accounts Receivable fr. Affil. Comp.	1410	-	-	-	-
Short-Term advances to Affiliates	1420	-	-	-	-
Other Assets	1500	9,738	25,242	3,446	(21,796)
Deferred Tax Assets	1510	33,915	25,000	51,370	26,370
Total Receivables	1590	80,708	170,521	111,194	(59,327)
Liquid Funds	1790	-	-	-	-
Prepaid Expenses a.o. deferred items	1890	343	125	439	314
Total Current Assets	1900	190,594	277,783	227,240	(50,543)
Total Assets	1000	332,840	466,753	393,751	(73,002)
<b>SHAREHOLDERS' EQUITY, PROVISIONS, AND LIABILITIES</b>					
Share Capital	2010	19	19	19	-
Additional Paid-In Capital	2020	8,735	8,735	8,735	-
Retained Earnings, Opening Balance	2200	46,121	60,599	46,121	(14,478)
Interim Dividends	2207	-	-	-	-
Net Income (Loss), Current Period	2210	19,269	20,462	5,320	(15,142)
Total Shareholders' Equity	2300	74,144	89,815	60,195	(29,620)
Provision for Pensions	2410	17,195	24,000	21,102	(2,898)
Tax Provisions	2450	59,924	17,000	34,166	17,166
Deferred Tax Prov/Liabilities	2470	12,837	-	18,025	18,025
Other Provisions and Accruals	2500	70,466	73,024	71,975	(1,049)
Total Provisions	2600	160,422	114,024	145,268	31,244
Trade Accounts Payable	2610	19,591	48,776	24,761	(24,015)
Payable to Banks	2630	-	-	-	-
Payables to Affiliates	2720	6,650	9,000	71,428	62,428
Loans from Affiliates	2740	62,342	204,388	88,721	(115,667)
Other Liabilities	2820	87	750	153	(597)
Total Liabilities	2900	88,670	262,914	185,063	(77,851)
Deferred Income	2950	9,604	-	3,225	3,225
Total Liabilities and Provisions	2990	258,696	376,938	333,556	(43,382)
Total Equity, Liabilities and Provisions	2000	332,840	466,753	393,751	(73,002)

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Boehringer Ingelheim  
Roxane Laboratories

Actual 2004

**PNR 2720 & 2740: Payables to / Loans from Affiliates**

- Down \$53.2 Million.
  - Primarily due to the \$51 Million received from Elan in 2003 that had not been captured in Budget 2004.

**PNR 2950: Deferred Income a.o. Def. Credits**

- Up \$3.3 Million.
  - Expected payment which represents outstanding claims pending from the lawsuit settlement for Marinol returns, other returns and chargebacks.